K023398

Special 510(k) - SUMMARY

Discovery Package for Hologic QDR X-Ray Bone Densitometers

Submitter Name:	Hologic, Incorporated
Submitter Address:	35 Crosby Drive
	Bedford, MA 01730
Contact Person:	Daniel F. Phelan, Senior Regulatory Affairs Specialist
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Date Prepared:	October 1, 2002
Device Trade Name:	Discovery Package for Hologic QDR X-Ray Bone Densitometers
Device Common Name:	X-Ray Bone Densitometer
Predicate Devices:	K992677 Windows 98 "Eagle" Software for QDR Densitometers
	K992775 Assessment of Vertebral Deformities Using QDR Densitometers
K983028 Fracture Risk Estimation for QDR Densitometers	
	K963363 Reference Databases (NHANES Software) for QDR Densitometers
	K941362 Vertebral Morphometry Analysis Software for QDR Densitometers
	K943505 QDR 4500 X-Ray Bone Densitometer
	K913321 QDR 2000 X-Ray Bone Densitometer
	K894795 QDR 1000W X-Ray Bone Densitometer
	K883280 QDR 1000 X-Ray Bone Densitometer
	K001812 Pediatric Reference Data for Lunar Bone Densitometer
Device Description:	The Discovery Package for QDR Bone Densitometers is a software system that integrates all of the previously cleared features of prior versions of the QDR Densitometers in a Microsoft Windows XP operating environment.
Intended Use:	The intended use of the Discovery Package for QDR X-Ray Bone Densitometers is the estimation of bone mineral density (BMD), comparison of measured variables obtained from a given QDR scan to a database of reference values, the estimation of fracture risk, vertebral deformity assessment, body composition analysis, and discrimination of bone from prosthetics using the Hologic QDR® X-Ray Bone Densitometers.

NOV 8 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2002

Mr. Richard L. Follett
Vice President, Regulatory Affairs
And Quality Assurance
HOLOGIC, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K023398
Trade/Device Name: Discovery Package for Hologic QDR X-ray Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometers
Regulatory Class: II
Product Code: 90 KGI
Dated: October 1, 2002
Received: October 9, 2002

Dear Mr. Follett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

The Discovery Package for QDR X-Ray Bone Densitometers is indicated for the estimation of bone mineral density (BMD), comparison of measured variables obtained from a given QDR scan to a database of reference values, the estimation of fracture risk, vertebral deformity assessment, body composition analysis, and discrimination of bone from prosthetics using the Hologic QDR® X-Ray Bone Densitometers.

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Lyerman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023398